

### **REMARKS/ARGUMENTS**

Claims 1, 19-21, and 23-36 are pending and stand substantively rejected. Claims 2-18 and 22 were previously canceled. Reconsideration of the claims is respectfully requested. The paragraph numbering below follows that of the Detailed Action.

#### **Rejection Under 35 U.S.C. §102**

¶2. Claims 1, 19-21, 23-26, and 35 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by USPN 4,124,705 to Rothman et al. This rejection is traversed.

According to MPEP 2131, to anticipate a claim, a reference must teach all elements of the claim. Rothman fails to meet this test.

#### **Presently Pending Independent Claim 1**

Presently pending claim 1 is drawn to an extrudable fragmented biocompatible resorbable single phase aqueous colloid which is substantially free from a free aqueous phase.

#### **Rothman's Gel Contains A Free Aqueous Phase**

The Office Action at page 3, lines 10-12 alleges that Rothman's gel does not contain any free water. Specifically, the Office Action states that Rothman's gel can contain less than 98% by weight water, and concludes this "*implies*" the gel contains no free water. Applicants cannot agree. It is improper to assume that if an item contains a percentage of water by weight, the item therefore has no free water. For example, a water-soaked sea sponge may contain 98% water by weight, yet water contained in the sponge is in a free aqueous phase. Similarly, a bottle of mineral water may contain a 98% water by weight, yet water contained within the bottle is in a free aqueous phase.

#### **Inherency Not Established**

To the extent the Office Action relies on the doctrine of inherency, Applicants note the following requirements as set forth in MPEP 2112(IV). For example, the Office Action must provide rationale or evidence tending to show inherency. To establish inherency, the extrinsic evidence must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. In relying upon the theory of inherency, the Examiner must provide a basis in fact and/or

technical reasoning to reasonably support the determination that the allegedly inherent characteristic *necessarily flows* from the cited reference. There has been no showing that a single phase aqueous colloid which is substantially free from a free aqueous phase necessarily flows from Rothman.

#### **Rothman's Mesh**

Rothman's particles are describes as having a meshed three dimensional network of polysaccharide molecules, for example at col. 5, lines 1-5, and col. 6, lines 6-7. However, it has not been shown that this three dimensional network presents a single phase aqueous colloid which is substantially free from a free aqueous phase, as presently claimed.

#### **Rothman's Solution Contains Free Water**

The Office Action at page 3, lines 15-18, alleges that Rothman's gel does not contain any free water, as follows:

"The particulate suspension containing polysaccharide particles [...] read on a single phase aqueous colloid [...] and hence the presence of aqueous solution (for suspending the particles) and hence read on the claimed 'free from a free aqueous phase'".

It is thus not clear which aspect of Rothman the Office Action proposes to read on the presently claimed colloid: Rothman's gel particle, or Rothmans' gel particle as suspended in solution. Regardless, when considering Rothmans' gel particle in suspension, this mixture clearly cannot read on the presently claimed colloid, because the suspension contains a free aqueous phase. More specifically, Rothman describes a composition that is a suspension of particles in an aqueous liquid. See, for example, col. 1, lines 58-68; col. 19, lines 61-63; col. 20, lines 26-30; and claims 1, 2, and 17. A suspension typically includes a mixture of a discontinuous solid particles interspersed within a continuous liquid that can be separated by mechanical means. Hence, the Rothman composition contains a free aqueous phase, and Rothman is not an anticipatory reference.

Presently pending dependent claims 19-21 and 23-26 depend from base claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the novel combination of elements they recite.

Presently Pending Dependent Claims 20 and 24

The single phase aqueous colloid of current claims 20 and 24 has an equilibrium swell from 400% to 5000%. The Office Action has not shown that Rothman teaches or suggests such an equilibrium swell.

Hence, the §102 rejection of claims 20 and 24 is not supported with any evidence or argument that this element is taught by Rothman. Applicants are not given the opportunity to address real issues of patentability, and are not given enough information to assist with the identification of any clear issues for appeal. Because the anticipation assertion is made without support in the record, it fails to meet the initial burden of factually supporting a conclusion of anticipation. Applicants should not be left to guess which features of the cited reference are alleged to read on presently pending claims 20 and 24.

Presently Pending Independent Claim 35

Current claim 35 recites a single phase aqueous colloid which is substantially free from a free aqueous phase, and thus is allowable for at least the reasons give above. Withdrawal of this rejection is respectfully requested.

**First Rejection Under 35 U.S.C. §103**

¶5. Claims 1, 19-21, 23-26, 34, and 36 were rejected under 35 U.S.C. §103(a) as allegedly obvious in view of USPN 4,482,386 to Wittwer et al. This rejection is traversed.

According to MPEP 2143, to support a *prima facie* case of obviousness it is important to identify a reason that would have prompted the artisan to combine the elements in the way the presently claimed new invention does. Moreover, all claim elements must be considered when determining patentability against the cited references. It has not been shown that Wittwer meets this test.

Presently Pending Independent Claim 1

Presently pending claim 1 is drawn to an extrudable fragmented biocompatible resorbable single phase aqueous colloid which is substantially free from a free aqueous phase.

Wittwer describes a water-swellaable hydrocolloid. However, it has not been shown that Wittwer describes a single phase aqueous colloid which is substantially free from a free aqueous phase, as presently claimed.

The single phase aqueous colloid recited in current claim 1 also possesses at least one of the following characteristics: (a) a subunit size when fully hydrated in the range from 0.01 mm to 5 mm, (b) an equilibrium swell from 400% to 5000%, and (c) an *in vivo* degradation time of less than one year.

As noted in the Office Action, claim 6 of Wittwer describes a particle size of 0.2 to 4 mm. However, it has not been shown that this particle size refers to a fully hydrated particle. Further, the Office Action is silent as to how Wittwer is supposed to describe an equilibrium swell from 400% to 5000%. Still further, the Office Action says "the property of degradation is associated with gelatin," but provides no evidence that Wittwer describes an *in vivo* degradation time of less than one year as presently claimed.

Based on the above, no reason has been identified that that would have prompted the artisan to combine the elements in the way the presently claimed new invention does. Moreover, all claim elements have not been considered by the Office Action. Hence, a *prima facie* case of obviousness has not been established with regard to current claim 1.

Presently pending dependent claims 19-21 and 23-26 depend from base claim 1, and are therefore allowable as depending from an allowable base claim, as well as for the nonobvious combination of elements they recite.

Presently Pending Independent Claims 34 and 36

Current claims 34 and 36 recite a single phase aqueous colloid, and thus is allowable for at least the reasons give above. Withdrawal of this rejection is respectfully requested.

**Second Rejection Under 35 U.S.C. §103**

¶6. Claim 27 was rejected under 35 U.S.C. §103(a) as allegedly obvious over Rothman in view of USPN 4,515,637 to Cioca. This rejection is traversed.

As noted above, Rothman does not teach or suggest a single phase aqueous colloid substantially free from a free aqueous phase, as recited in independent claim 1. Cioca has not been shown to remedy this deficiency. Hence, the two references do not suggest the presently claimed combination of elements of base claim 1, or claim 27 which depends therefrom. Withdrawal of this rejection is requested.

**Third Rejection Under 35 U.S.C. §103**

¶7. Claims 28-33 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Rothman in view of Wittwer and USPN 6,129,761 to Hubbell. This rejection is traversed.

As noted above, Rothman and Wittwer do not teach or suggest a single phase aqueous colloid substantially free from a free aqueous phase, as recited in independent claim 1. Hubbell describes a hydrogel containing the cells, and therefore does not remedy this deficiency. Hence, the three references do not suggest the presently claimed combination of elements of base claim 1, or claims 28-33 which depend therefrom. Withdrawal of this rejection is requested.

**Fourth Rejection Under 35 U.S.C. §103**

¶11. Claims 25-29 were rejected under 35 U.S.C. §103(a) as allegedly obvious over Wittwer in view of Rothman and Cioca. This rejection is traversed.

As noted above, Rothman, Wittwer, and Cioca do not teach or suggest a single phase aqueous colloid substantially free from a free aqueous phase, as recited in independent claim 1. Hence, the three references do not suggest the presently claimed combination of elements of base claim 1, or claims 25-29 which depend therefrom. Withdrawal of this rejection is requested.

**CONCLUSION**

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 303-571-4000.

Respectfully submitted,

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